K040888 1/2

DEC - 1 2004

510(k) Summary of Safety and Effectiveness

Applicant Name and Address:	Collagen Matrix, Inc. 509 Commerce Street Franklin Lakes, New Jersey 07417
Contact Person:	Peggy Hansen, RAC Director, Clinical, Regulatory, and Quality Assurance Tel: (201) 405-1477 Fax: (201) 405-1355
Date of Summary:	April 1, 2004
Device Common Name:	Collagen Dura Substitute Membrane
Device Trade Name:	DuraMatrix™ Collagen Dura Substitute Membrane
Device Classification Name:	Dura substitute Class II 8882.5910 GXQ
Predicate Device(s):	Dura-Guard® Dural Repair Patch, K950956 DuraGen® Dural Graft Matrix, K982180

Description of the Device

The Collagen Dura Substitute Membrane is a white, nonfriable, conformable, resorbable, membrane matrix engineered from highly purified type I collagen derived from bovine Achilles tendon. The device has a thickness similar to that of native dura. It is flexible and conforms to the contours of the defect site. The unique conformability properties of the membrane combined with its mechanical strength allow the membrane matrix to be applied as an onlay membrane or sutured in place. The Collagen Dura Substitute Membrane is supplied sterile, non-pyrogenic, in various sizes, and for single use only.

Intended Use

The Collagen Dura Substitute Membrane is indicated for use as a dural substitute for the repair of dura mater.

Summary/Comparison of Technical Characteristics

Collagen Dura Substitute Membrane and its predicates have similar technological characteristics. In particular, the Collagen Dura Substitute Membrane and its predicates

are similar with respect to intended use, material, form, sizes, thickness, physical integrity, porosity and conformability.

Safety

Collagen Dura Substitute Membrane has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Effectiveness

The results of a large-scale animal study and clinical study support the effectiveness of using a membrane material as a dura substitute in the repair of dura mater. The characteristics of the Collagen Dura Substitute Membrane meet the design requirements for an effective dura substitute.

Conclusion

The results of the *in vitro* product characterization studies, *in vitro* and *in vivo* biocompatibility studies, large-scale animal study and clinical study show that the Collagen Dura Substitute Membrane is safe and substantially equivalent to Dura-Guard® Dural Repair Patch and DuraGen® Dural Graft Matrix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2004

Ms. Peggy Hansen, RAC
Director, Clinical, Regulatory, and Quality Assurance
Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K040888
Trade/Device Name: DuraMatrix™ Collagen Dura Substitute Membrane
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: October 25, 2004
Received: October 26, 2004

Dear Ms. Hansen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040888

Indications for Use

510(k) Number (if known): _____

Device Name: DuraMatrix™ Collagen Dura Substitute Membrane

Indications for Use:

DuraMatrix™ Collagen Dura Substitute Membrane is indicated for use as a dural substitute for the repair of dura mater.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040888